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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/479,467	01/06/2000	Paul W Sternberg	18021-2919	3063

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EXAMINER	
PARAS JR, PETER	

ART UNIT	PAPER NUMBER
1632	21

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/479,467	Applicant(s) STERNBERG ET AL.
	Examiner Peter Paras, Jr.	Art Unit 1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 January 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on ____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): ____.

4. ☐ Newly proposed or amended claim(s) ____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: ____.

   Claim(s) objected to: *21,22,25,26 and 49*.

   Claim(s) rejected: *1,5,9-11,15-17,27-32,42,74-77 and 82-84*.

   Claim(s) withdrawn from consideration: *88-89*.

8. ☐ The proposed drawing correction filed on ____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). ____.

10. ☐ Other: ____

Continuation of 2. NOTE: claim 9 as amended now recites a gene that comprises the sequence of amino acids set forth in SEQ ID NO: 4. The claim as amended raises new grounds of rejection under 112, 2nd paragraph because a nucleic acid sequence cannot comprise an amino acid sequence.

Continuation of 5. does NOT place the application in condition for allowance because: claims 27-32, 42, 74-77, and 82-84 are still rejected under 112, 1st paragraph for lack of guidance and working examples for the production of a transgenic Caenorhabditis nematode. Applicants have argued that the instant specification has taught transgenic nematodes with observable phenotypes. See page 10 of the amendment after final. The Examiner concedes that the instant specification has enabled the production of a transgenic C. elegans comprising a nucleotide sequence that encodes a truncated LOV-1 protein (the construct used was plov-1.3, see page 48 of the specification) that when expressed acts as a dominant negative resulting in a phenotype of altered location of vulva and defective mating behavior. The claims however, are much broader than such a scope because they are not limited to a particular transgene construct (for example plov1.3). Other transgenic nematodes that encompass wild-type Lov-1 coding sequences or other mutant Lov-1 coding sequences are not enabled. For example, Applicants have argued on page 11 of the amendment after final that plov1.1 when introduced into an sy552 mutant, having a phenotype of altered location of vulva and defective mating behavior, rescues the mutant phenotype. The Examiner argues that the rescued nematode has a normal pheonotype and is not distinguishable from a wild-type nematode. As such it is not clear what differences exist between a wild-type nematode and the "rescued" nematode. Next, Applicants have pointed to Examples 1 and 2 of the specification for support of their assertions that many examples of transgenic nematodes have been presented. In response, the Examiner asserts that in these examples different regions of the Lov-1 coding sequences were injected into sy552 mutant nematodes, wherein the full length lov-1 coding sequence rescued the mutant phenotype (previously discussed) and the other sequences did not produce a different phenotype. As the resulting transgenic nematodes either have a wild-type phenotype or the same mutant phenotype it is not clear how they differ from wild-type or sy552 mutagenized nematodes. Furthermore, claims 31 and 32 are directed to transgenic nematodes that comprise a nucleic acid molecule that encodes a mutant lov-1 protein. However the recited nematodes actually comprise a wild-type lov-1 coding sequence as they comprise the nucleic acid sequence of claim 1. It is unclear how a nucleotide sequence can be both wild-type and mutant, wherein a mutant phenotpye is produced when such is expressed in a transgenic nematode, particularly because claim 1 required that a normal phenotype is produced when said sequence is expressed in a transgenic nematode. Finally, it is not clear if the mutant transgenic nematode produced from expression of plov-1.3 transmits the transgene through the germline to produce a line of transgenic nematodes. If the transgene is not transmitted through the germline, then production of transgenic nematodes comprising plov-1.3 is not reproducible as different transgenic nematodes must be produced for further experimentation. The different transgenic nematodes could have different phenotypes resulting from the unpredictability of transgenic expression. See pages 4-5 of the Office action mailed on 7/31/01. It is maintained the the specification has not provided any working examples that demonstrate identification of gene and regulatory factors involved in polycystic kidney disease using mutant C. elegans. The specification has failed to establish a correlation between any nucleic acid sequence isolated by the claimed methods (claims 74-77 and 82-84) and polycystic kidney disease. See page 5 of the Office action mailed on 7/31/01. Claims 9-11 are rejection under 112, 2nd paragraph as it is maintained that the term "gene" is indefinite. Applicants have argued that the term is not indefinite as the instant specification has taught the intron/exon boundaries of the lov-1 gene as well as the promoter region of the same. Applicants have pointed to figure 2b and figures 3-4 as well as page 37 for support respectively. In response, the Examiner asserts that figure 2b has disclosed only 3 actualy exons while providing general information as to the existence of other putative exons. The Examiner asserts that figures 3-4 do not teach the promoter sequence for the lov-1 coding sequences; page 37 teaches that a 2.8KB upstream sequence can direct expression of a reporter gene, however it is not clear if such is the full length promter or only a fragment. Claims 1, 5, 9-11, and 15-17 are rejected under 102(b) as being anticipated by Wilson et al. Applicants have argued that the sequence of Wilson et al is not the same as SEQ ID NO: 3, particularly because the Wilson sequence is shorter than SEQ ID NO: 3. Applicants have also argued that the Wilson sequence lacks some of the coding regions of lov-1. See pages 26-28 of the amendment after final. In response, the Examiner maintains that the sequence of Wilson anticipates the claims because it is not clear if coding sequences are actually missing from the Wilson sequence as the coding sequences have not been elucidated by the instant specification; only putative or predicted exons have been discussed by the specification (for example see figure 2B). Also as the two sequences share 100% local similarity there can be no doubt that the sequence of Wilson encodes a lov-1 protein or that the sequence of Wilson would hybridize to the sequence of SEQ ID NO: 3 or that the sequence of Wilson is the complement of a sequence of nucleotides set forth in SEQ ID NO: 3. As the sequence of Wilson has met these claim requirements it would be inherent that the sequence of Wilson has the functional properties recited in claim 1.

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